

Creating a Content of Labeling/ Drug Listing SPL Document – Drug Products

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Components of Rx SPL File

- Content of labeling
- Carton or container label(s)
- Product Data Elements (drug listing)

Proprietary Name

Product Information

Proprietary Name

Betamethasone Dipropionate

- The proprietary name is the brand or trade name **without additional qualifiers** such as “extra strength” or “XR”.
- For drug products which do not have a proprietary name, include the non proprietary name without additional qualifiers as the proprietary name.
- Enter the proprietary name. If there is a suffix, leave a space after the name.

Proprietary Name Suffix

Proprietary Name Suffix

- The proprietary name suffix is **the additional qualifiers** added to the proprietary name.
- If there are no additional qualifiers, then leave suffix field empty.

Non-proprietary Name

Non-Proprietary Name

betamethasone dipropionate

- Enter name(s) of **active ingredient(s)** in the non-proprietary name field in product data elements section.
- **DO NOT** include “USP” in the non-proprietary field in the product data elements section


NDC Product Code

NDC Product Code

11445-123

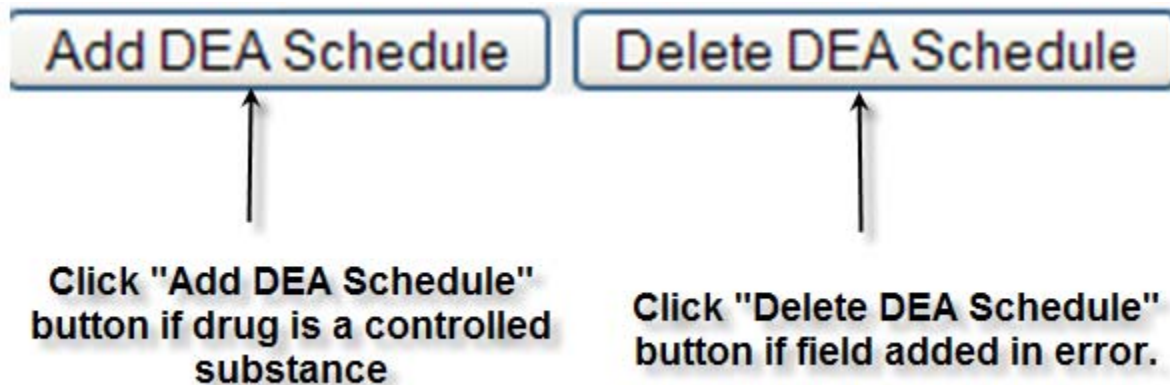
- The NDC Product Code is the NDC Labeler Code and the product code segment of the NDC separated by a hyphen.
- Enter the NDC Product Code

Dosage Form

Product Information	
Dosage Form	CREAM 

- The dosage form of the drug product is the physical form as packaged.
- Select the appropriate dosage form from the drop down list.

DEA Schedule



- Click “Add DEA Schedule” button, if applicable.
- From the drop-down menu, select the appropriate DEA schedule for the drug product

Route of Administration

Route of Administration	TOPICAL	▼
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- Click “Add Route of Administration” button
- Select the route of administration applicable for drug product.
- Click “Add Route of Administration” button again to add more routes, if applicable.

Active Ingredients



- Click “Add Active Ingredient” button if there are active ingredients.
- Select “Delete Active Ingredient” button if chosen in error.
- Select “Add Active Ingredient” button for each active ingredient.

Active Ingredient Name

Active Ingredient	
Name	betamethasone dipropionate

- Enter active ingredient name (preferred name) without additional qualifiers such as “USP,” “NF,” etc...

Adding UNII for Active Ingredient

Active Ingredient	
Name	betamethasone dipropionate
Unique Ingredient Identifier (UNII)	826Y60901U




Enter UNII for active ingredient

- Enter the preferred name and Unique Ingredient Identifier (UNII) for the active ingredient.
- Select UNII from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/Structure dProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.

Strength of Active Ingredient

Active Ingredient			
Name	betamethasone dipropionate		
Unique Ingredient Identifier (UNII)	826Y60901U		
Strength	0.64	mg	in 1 g

Enter strength as ratio
Use metric units



- Strength is represented as a ratio.
- The numerator and denominator have a value and a unit.
- The value is the amount of ingredient for a dose (usually a whole number) based on either the active ingredient or active moiety.
- Enter the value and select the appropriate unit for the numerator and denominator for the strength.

Active Moiety Name

Active Moiety	
Name	betamethasone

- There are one or more active moieties for each active ingredient.

Entering UNII for Active Moiety


Active Moiety	
Name	betamethasone
Unique Ingredient Identifier (UNII)	9842X06Q6M
<input type="button" value="Add Active Moiety"/> <input type="button" value="Delete Active Moiety"/>	

Enter UNII for active moiety

- Enter the preferred name and UNII for the active moiety for the active ingredient.
- Select UNII from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.
- Click “Add Active Moiety” button to include additional active moieties.

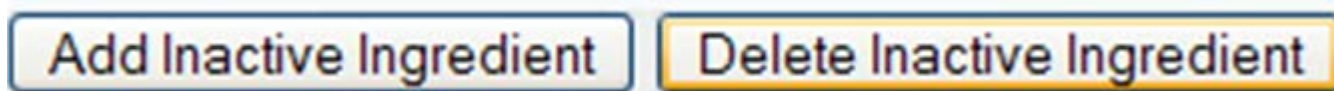
Basis of Strength

Basis of Strength

Active Ingredient 

- Select if the active ingredient or active moiety is used as the basis of the strength of the drug.

Adding Inactive Ingredients



- Click the “Add Inactive Ingredient” button to add inactive ingredient name(s) and UNII(s), if applicable.


Inactive Ingredients

Inactive Ingredient	
Name	Water

- Enter inactive ingredient name (preferred name)

Adding UNII for Inactive Ingredient

Inactive Ingredient	
Name	Water
Unique Ingredient Identifier (UNII)	059QF0KO0R



Enter the UNII for the inactive ingredient.

- Enter the preferred name and Unique Ingredient Identifier (UNII) for the inactive ingredient.
- Select UNII from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.

Marking the Inactive Ingredient as Confidential

Inactive Ingredient	
Name	Water
Unique Ingredient Identifier (UNII)	059QF0KO0R
Mark as Confidential	<input type="checkbox"/>



Check the box if the inactive ingredient is confidential

- Check if the inactive ingredient is to be considered as confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.

Adding the Strength for an Inactive Ingredient.




- To add the strength for an inactive ingredient, click the “Add Strength” button.
- To remove the strength of an inactive ingredient, click the “Delete Strength” button.
- If applicable, follow the instructions for including strength for an active ingredient.

Adding a Flavor



- Flavors are described as product distinctive characteristics rather than ingredients.
- **If applicable**, add a flavor by clicking the “Add Flavor” button.
- To remove a flavor, click the “Delete Flavor” button.


Selecting a Flavor

Flavor	
Name	COFFEE 

- Select a flavor from the flavor “Name” drop-down menu.
- If flavor and/or original text are **not needed**, **delete the field**.

Adding Flavor Original Text

Flavor	
Name	COFFEE
Original Text	Coffee Flavor



Enter free text to include additional description of flavor.

- Enter additional description of the flavor into the original text field.

Adding a Color



- **If applicable**, to add a color, click the “Add Color” button.
- To remove a color, click the “Delete Color” button.
- More than one color can be added for each product, if applicable.

Selecting a Color



A screenshot of a web form. On the left, there is a light blue rectangular label with the word "Color" in a dark blue font. To the right of this label is a white rectangular input field. Inside this field, the word "blue" is written in a dark blue font. To the right of the input field is a small blue square button with a white downward-pointing arrow, indicating a dropdown menu.

- Select a color from the “Color” drop-down menu.
- If applicable

Adding Original Text for Color

Color	blue
Original Text	Sky Blue



Type as free text additional description for color.

- Enter additional description of the color into the original text field.
- If color and/or original text are not needed, delete the field.
- If applicable

Adding Imprint Information



- Click “Add Imprint” button for describing **solid oral dosage form** product characteristics.
- **If not applicable**, select the “Delete Imprint” button if “Add Imprint” button is chosen in error.

Score



The image shows a web form element. On the left, there is a light gray rectangular label with the text "Score" in a bold, black, sans-serif font. To the right of this label is a dropdown menu. The dropdown menu has a blue border and contains the text "Two even pieces" in a black, sans-serif font. To the right of the text is a small blue square button with a white downward-pointing chevron. A black arrow points from the text "Select appropriate score value." below to the dropdown menu.

Select appropriate score value.

- If applicable
- Select the appropriate score
 - no score = 1
 - scoring with two equal pieces = 2,
 - scoring with three equal pieces = 3,
 - scoring with four equal pieces = 4,
 - other = nullFlavor = OTH).


Selecting a Shape



- Select the appropriate shape from drop-down list.
- If applicable

Adding Original Text for Shape

Shape	OVAL
Original Text	Capsule



Enter additional descriptive information for shape.

- Enter additional description of the shape into the original text field.

Entering Imprint Information

Imprint Code

3:hp;x

- **IF APPLICABLE**, Enter the imprint code by beginning on either side or part of the dosage form.
- Start at the top left and progress as one would normally read a book.
- **Enter a semicolon to show separation between words or line divisions.**
- If there is no imprint code, **leave the field blank.**

Entering the Size

Size

19

- Size is represented by the longest single dimension of the solid dosage form as a physical quantity in the dimension of length (e.g., 19 mm).
- Enter the value rounded to the nearest whole number in the size field
- If applicable

Entering the Size Unit

Size Unit	mm
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- Enter mm in the size unit field.
- If applicable

Product Data Elements

These highlights do not include all the information needed to use Cymbalta safely and effectively - Windows Internet Explorer

C:\Documents and Settings\smithlo\Desktop\w_location\2011_spl_training_sessions\source_files\2222222-1111-f212-5921-59381df221e1.xml

File Edit View Favorites Tools Help

Product Data Elements Form

PROPRIETARY NAME PROPRIETARY NAME SUFFIX (IF NECESSARY)
active ingredient name(s) here dosage form

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:1111-2222
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
active ingredient name (active moiety)	active moiety	20 mg

Inactive Ingredients

Ingredient Name	Strength
inactive ingredient	
inactive ingredient	

Product Characteristics

Color	green (green)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	20;mg
Contains			

Done

start 14 M... 5 I... 7 C... 8 W... 2 M... 3 M... 2 A... Altov... My Computer 100% 10:00 AM

Application Number

- Application numbers include the character application abbreviation and the numbers without spaces or dashes (e.g., NDA123456).
- Unapproved drugs – Use the “unapproved drug other” marketing category – DO NOT enter an application number

Content of labeling

- Sections
- Subsections
- Hyperlinks (only if applicable)
- Highlights text (labels in Physician Labeling Rule format)

Highlights Title

- If there are highlights (PLR format), then the title for the SPL file includes the text string (without quotation marks): “These highlights do not include all the information needed to use” “see full prescribing information for” and “Initial U.S. Approval”

Adverse Reactions Section (PLR Format Only)

- An excerpt in the adverse reactions section (34084-4) includes the statement "to report suspected adverse reactions" and "1-800-FDA-1088" (different telephone numbers for documents of type 53404-0 – "Vaccine Label").
- For PLR format labels

SPL Submission for Application Product Listing in Electronic Format

Submission

Applicant

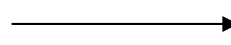
FDA

Public

Application

Prior approval

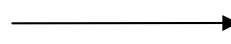
SPL release 4



EDR

CBE, FS, annual report

SPL release 4

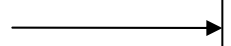


EDR

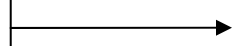
Listing

CBE, FS, annual report

SPL release 4

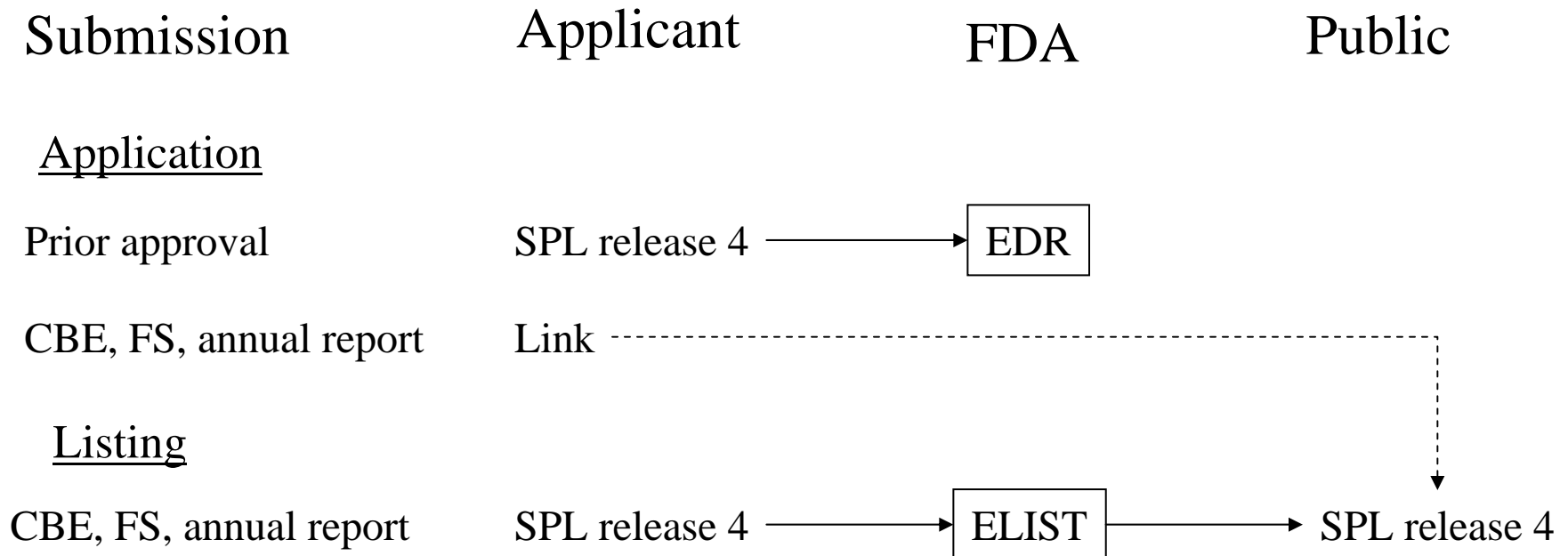


ELIST



SPL release 4

Application Product Listing in Electronic Format with Link to Posted SPL file (when file submitted via eListing Process)



Referencing “Application Product” SPL

- Referencing the identical content of labeling submitted during listing process
- Include a statement and hyperlink in your application submission
- (e.g., “We have submitted the SPL file with drug listing; it can be found at the following location <http://www.accessdata.fda.gov/spl/data/> [*insert your SPL document id root here/insert SPL document id root here*].xml”]

OTC SPL

Components of OTC Drug Listing

- Drug Facts (content of labeling)
- Carton or container images
- Product Data Elements (drug listing)

Drug Facts

- Sections of the drug facts label entered as text into the appropriate sections
- Select the appropriate section header (e.g. OTC Purpose (different than section title))
- Do not submit content of labeling text as an image (copy and paste text into appropriate fields)

Carton/Container Images

- Representative sample of carton or container image
- Place image reference in the section **AFTER** the drug facts sections

Drug Facts Example

(snapshot of half of fictitious label)

PROPRIETARY NAME HERE SUFFIX HERE - active ingredient name here tablet
Labeler name here

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient(s)

Information required in 201.66(c)(2)

Purpose

Information required in 201.66(c)(3)

Use(s)

Information required in 201.66(c)(4)

Warnings

Applicable warning(s) in 201.66(c)(5)(i) and (ii)

Do not use

Information required in 201.66(c)(5)(iii)

Carton/Container Image

Inactive ingredients

Information required in 201.66(c)(8)

Questions

Information specified in 201.66(c)(9)

Principal Display Panel

OTC Medicine

Long Acting

Fast Relief

4 FL OZ (118 mL)



Carton/Container Image cont...



Homeopathic SPL

Components of Homeopathic Drug Listing

- Drug Facts (content of labeling) (OTC)
- Package insert (Rx)
- Carton or container images
- Product Data Elements (drug listing)

Active Ingredient

- The active ingredient includes the active ingredient name and identifier (Unique Ingredient Identifier (UNII) , strength, and the active moiety names and identifier (UNII). All active ingredients have at least one active moiety (in some cases two active moieties). Names of active ingredient **should not include designations such as USP or NF**. The name is taken from controlled terminology. Only terms in the controlled terminology are allowed. For ingredients, the controlled terminology is found in the FDA Substance Registration System/Ingredient Dictionary (SRS/ID). The **UNII is linked to the name** of the ingredient.
- Active moieties - more than one active moiety can be included for each active ingredient.

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
name(s) of active ingredient(s) (name of active moiety number 1 and name of active moiety number 2)	name(s) of active ingredient(s)	50 mg

Active Ingredients – Homeopathic Drug Products

- Do not repeat the same active ingredient in a product data elements section.
- Enter the largest amount of active ingredient in the product for homeopathic drug products only – Product Data Elements section ONLY

UNIIs

- Select UNIIIs from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.
- Request all UNIIIs needed to list your products as soon as possible.

Homeopathic Units of Measure

UCUM Name	UCUM
HOMEOPATHIC POTENCY OF CENTESIMAL SERIES	[hp_C]
HOMEOPATHIC POTENCY OF CENTESIMAL KORSAKOVIAN SERIES	{kp_C}
HOMEOPATHIC POTENCY OF MILLESIMAL SERIES	[hp_M]
HOMEOPATHIC POTENCY OF QUINTAMILLESIMAL SERIES	[hp_Q]
HOMEOPATHIC POTENCY OF DECIMAL SERIES	[hp_X]

Repack/Relabel

Repack/Relabel

Content of Labeling

- Methods for providing the manufacturer's content of labeling
 - Create the content of labeling via data entry
 - Download current version of manufacturer's label from DailyMed (change document IDs and setIDs)

Repack/Relabel Medication Guides

- **ASAP!** - Please check all previously submitted SPL files to ensure that medication guide section are properly coded using the medication guide section header and code.

Doc IDs & SetIDs in Repacked Drug SPL Documents

- Change the doc IDs, section IDs, & setIDs of the manufacturer's SPL if you reuse their label (SPL).
- Once you submit your first valid version of the SPL with your setID, the setID must remain constant throughout lifecycle of SPL.
- Change the images of the carton/container labels to images of your carton/container labels

Repack/Relabel

DailyMed's RSS Feed

- DailyMed's Really Simple Syndication – automatic notification when your newly posted files or the manufacturer's newly posted files are available on DailyMed.
- Use to determine when original manufacturers' SPL files are updated.

Repack/Relabel

DailyMed's RSS Feed Info

- **DailyMed RSS Feed : Update Notices to Your Reader**
- <http://dailymed.nlm.nih.gov/dailymed/rsshome.cfm>
- **What is RSS?**
- RSS (Really Simple Syndication) is a format for sharing and distributing Web content. Using an RSS reader, you can get updates and information about new drug labels approved by the FDA and published on NLM's DailyMed Web site. RSS Readers (also called Aggregators) will download the DailyMed RSS feed for you.
- **How do I get a RSS Reader?**
- There are many free RSS Readers available for download via the Internet and more are added each day. They give you a variety of functions and each has its own advantages.
- NLM or DailyMed does not endorse any particular reader or aggregator. To find one that fits your needs simply search the Internet entering the key words *Free RSS Reader*. Or, you may select one of the RSS Reader applications here:

[List of RSS Readers - in the Internet Open Directory.](#)

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

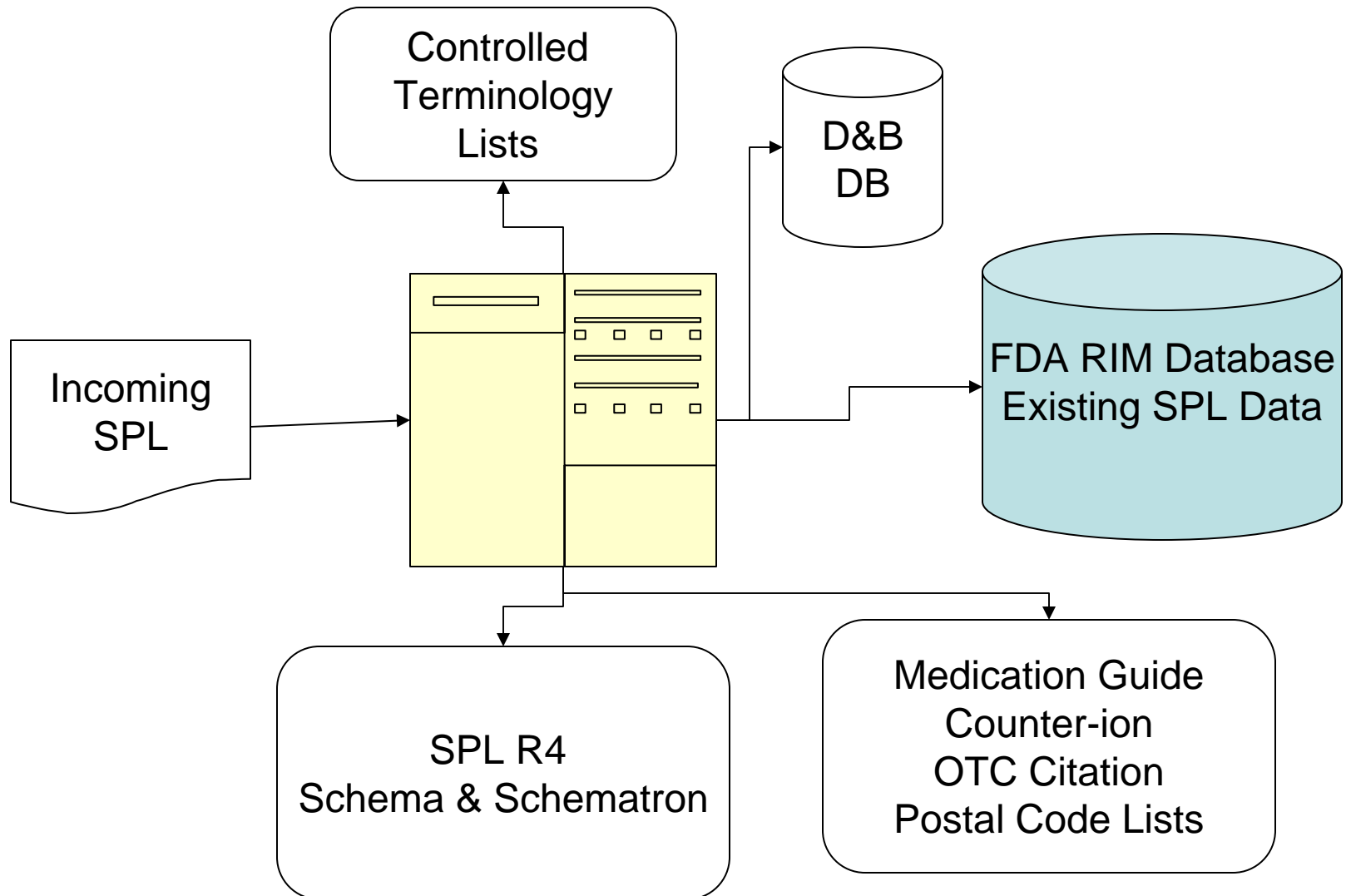
New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Updating SPL Document Tracking Information

- **Use**
 - **new** id root
 - **new** version number
 - original setId
 - appropriate effective time
- **Misplaced SetID/SPL File**
 - E-mail core ID to spl@fda.hhs.gov
- Include contact person's name and DUNS Number which were included in original SPL file

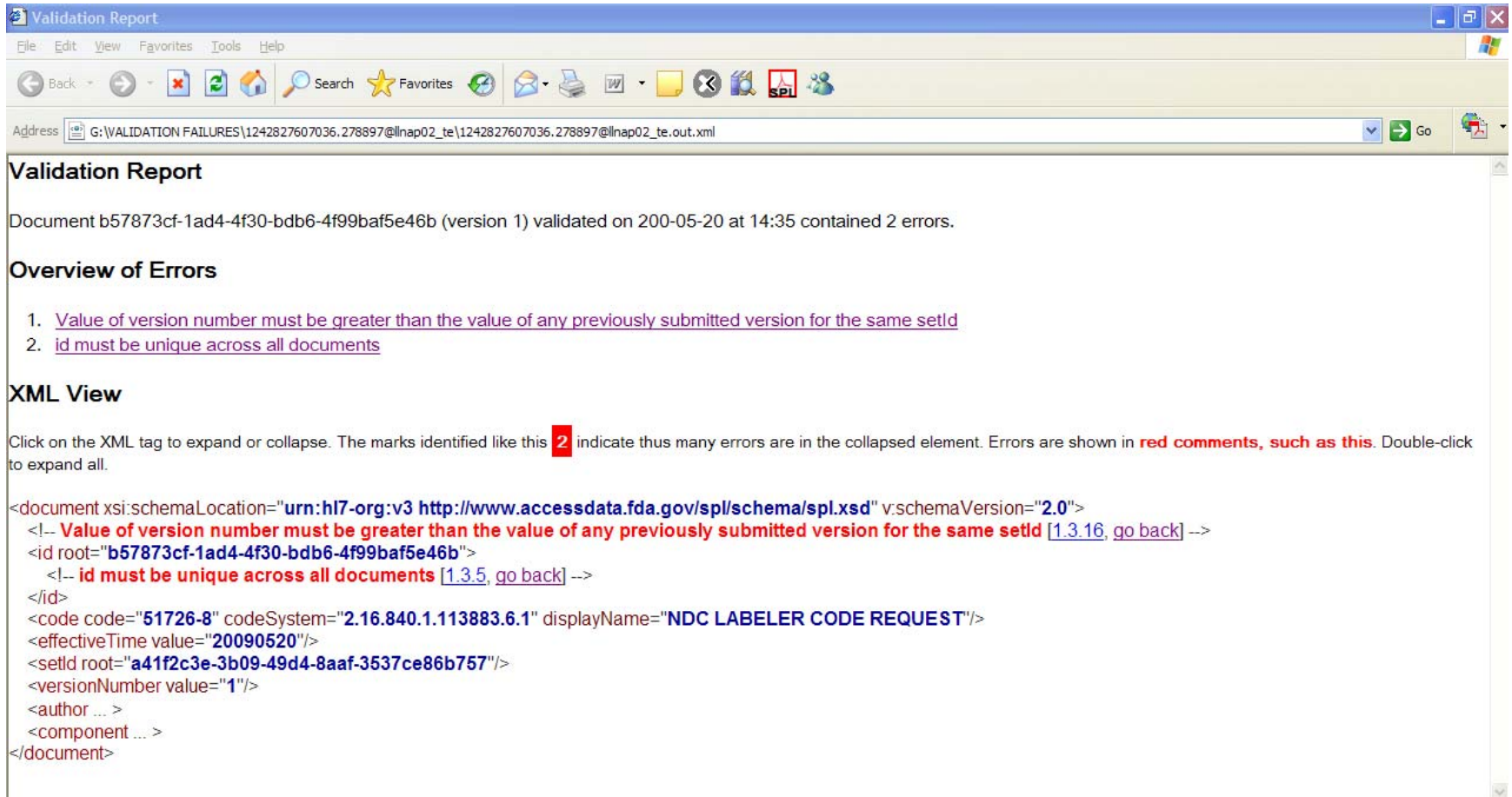
Validation Model



Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
 - 2nd acknowledgment – system-generated message
 - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

Sample System Generated Validation Report



Validation Report

Document b57873cf-1ad4-4f30-bdb6-4f99baf5e46b (version 1) validated on 200-05-20 at 14:35 contained 2 errors.

Overview of Errors

- [Value of version number must be greater than the value of any previously submitted version for the same setId](#)
- [id must be unique across all documents](#)

XML View

Click on the XML tag to expand or collapse. The marks identified like this **2** indicate thus many errors are in the collapsed element. Errors are shown in **red comments, such as this**. Double-click to expand all.

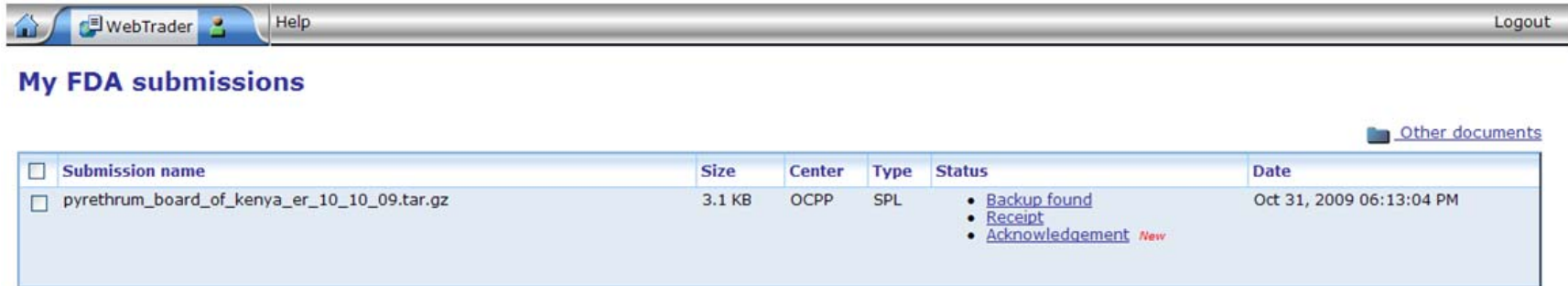
```
<document xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/spl/schema/spl.xsd" v:schemaVersion="2.0">
  <!-- Value of version number must be greater than the value of any previously submitted version for the same setId [1.3.16, go back] -->
  <id root="b57873cf-1ad4-4f30-bdb6-4f99baf5e46b">
    <!-- id must be unique across all documents [1.3.5, go back] -->
    </id>
    <code code="51726-8" codeSystem="2.16.840.1.113883.6.1" displayName="NDC LABELER CODE REQUEST"/>
    <effectiveTime value="20090520"/>
    <setId root="a41f2c3e-3b09-49d4-8aaf-3537ce86b757"/>
    <versionNumber value="1"/>
    <author ... >
    <component ... >
  </document>
```

Test Your SPL R4 Docs

- Provision of SPL R4 Validator Tool
- Test SPL R4 files prior to submission
- Discover ~90 – 95% of validation errors prior to submission.
- Schematron technology – permits quick updates to validation procedures
- FDA in collaboration with Pragmatic Data made available a validation tool:
[Pragmatic Validator Lite™](#)

Locating the Gateway Core ID

Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader' text, a user icon, 'Help', and a 'Logout' link. Below this is a section titled 'My FDA submissions'. To the right of this section is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. One submission is listed: 'pyrethrum_board_of_kenya_er_10_10_09.tar.gz' with a size of 3.1 KB, center OCPP, type SPL, and date Oct 31, 2009 06:13:04 PM. The status column for this submission contains three links: 'Backup found', 'Receipt', and 'Acknowledgement' (marked as 'New').

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

Selecting the File w/Core ID

Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink

- The **first** "Acknowledgment" link should take you to window with core ID.

Finding the Core ID

The screenshot shows a table with columns: Size, Center, Type, Status, and Date. The first row is highlighted with a blue background. Below the table, an 'Acknowledgment' window is open, displaying email details. An arrow points to the Core ID in the top left of this window.

Size	Center	Type	Status	Date
3.1 KB	OCPP	SPL	<ul style="list-style-type: none">Backup foundReceipt	Oct 31, 2009 06:13:04 PM

[close](#)

ci1257027185381.4044@lntap02_te.txt



From: [FDATST](#)
To: [Lonnie Smith \(FDA\)](#)
Date: Oct 31, 2009 06:16:03 PM EDT
Submission messageID: <7346727.1257027182095.JavaMail.smithlo@cdl0080685>
[View document](#)

This is the core ID

- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

Downloading Error Messages


Finding Error Messages

 WebTrader 

Help

Logout

My FDA submissions


 [Other documents](#)

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgementAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

Selecting Error Message

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement• Acknowledgement New	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

Opening Error Messages

The screenshot shows a web interface with a table of messages and a detailed view of a selected message.

Size	Center	Type	Status	Date
3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

[close](#)

ci1257016187076.9279@lntap01_te.xml

2.8 KB O

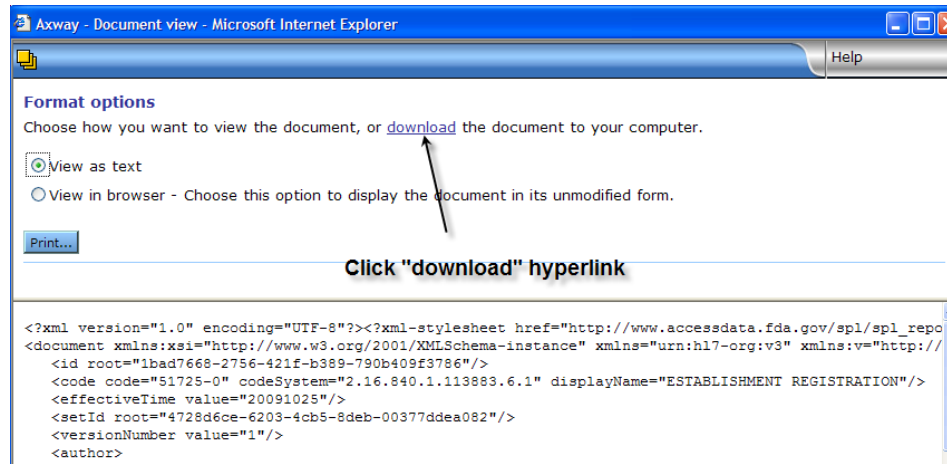
From: [FDATST](#)
To: [Lonnie Smith \(FDA\)](#)
Date: Nov 1, 2009 12:34:11 PM EST
Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>
[View document](#)

2.7 KB O

Click "View document" hyperlink

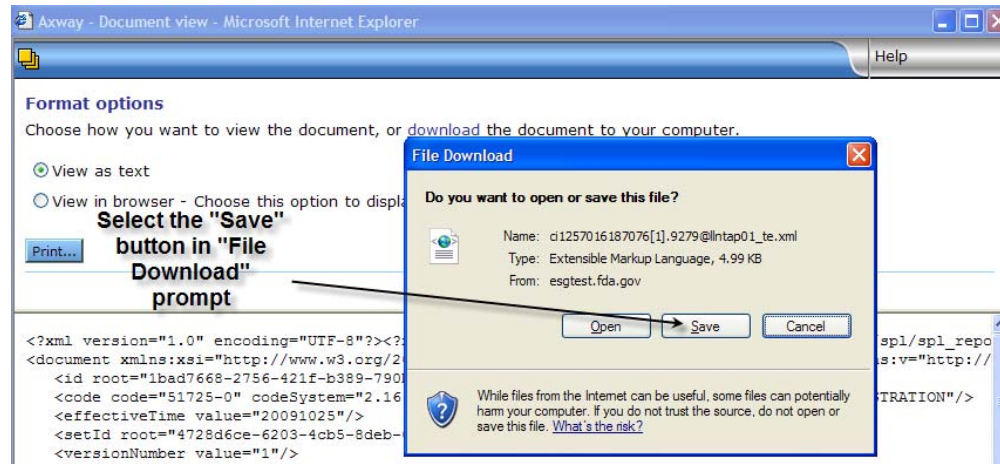
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message



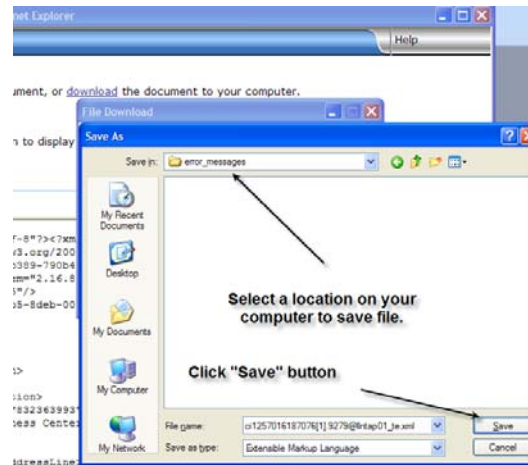
- Select the “download” hyperlink to download the error message to location on computer

Saving the Error Message Document



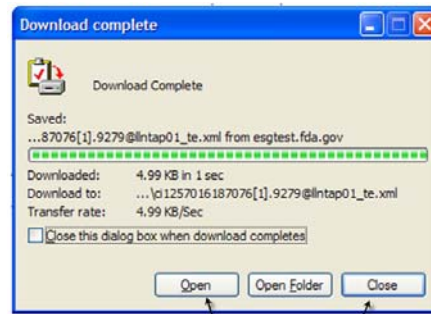
- Click the “Save” button in the “File Download” window prompt.

Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

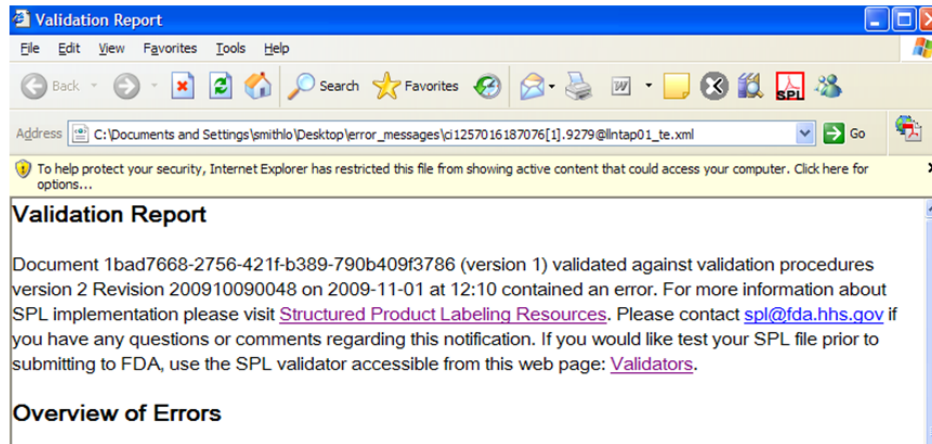
Completing Download



Select "Open" or "Close" buttons

- You can open the message from the "Download complete" window prompt
- You can also close the window and directly open from location on your computer where message was stored.

Review the Error Message



- Review the error message

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov link. Below is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph about the council's mission and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards
Validators
Data Council
Structured Product Labeling
Individual Case Safety Reports
Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)

QUESTIONS